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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

EVERINE VAN HOUTEN, Plaintiff, vs. USPlabs, LLC, a Texas corporation, and GNC Holdings, Inc., a Pennsylvania corporation, Defendants.	CIVIL NO. CV13-00635 LEK/KSC **MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

I. INTRODUCTION

Ms. Van Houten's claims against USPlabs, LLC and GNC Holdings, Inc. rest on one allegation, an alleged association between the use of a dietary supplement, OxyElite Pro, and liver injury.[1] However, Ms. Van Houten has failed to adduce ***any*** expert evidence regarding causation – either that OxyElite is generally capable of causing liver failure, or that it did so in Ms. Van Houten's specific case. Hawaii law requires, at minimum, ***some*** expert evidence to establish both facets of medical causation. Ms. Van Houten is now precluded from introducing expert testimony because the deadline to do so expired in March.

Even assuming Ms. Van Houten could prove a general causal connection,

[1] Throughout this motion, USPlabs, LLC and GNC Holdings, Inc. shall be referred to as **USPlabs** and **GNC**, respectively, or together, the **Defendants**. OxyElite Pro shall be referred to as **OxyElite** or the **Product**.

the undisputed evidence demonstrates that the source of her alleged injuries pre-dates her OxyElite consumption by at least two years. In April of 2011, Ms. Van Houten underwent a cholecystectomy, removing her gallbladder to address recurring abdominal pain and nausea, which are symptoms of gallstone disease. The surgery was no without complications. There were symptoms consistent with a retained stone, and, more significantly, a remnant of the cystic duct was left behind.[2]

Even if such surgery is successful, individuals with gallstone disease remain prone to developing stones—and thus blockages—in their common bile duct. Significantly, bile duct obstructions may result in abdominal pain and abnormal liver tests. As a result, bile duct blockages, like those Ms. Van Houten sustained throughout 2013, to a very high degree of medical certainty, are responsible for the alleged injuries in this case.[3]

In fact, the specific ingredient Ms. Van Houten implies caused her injury, Aegeline, is derived from the Bael tree, the leaves and fruit of which have been consumed for centuries.[4] Several preclinical studies show that Aegeline is not liver toxic, and no epidemiologically valid study or report indicates otherwise.

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[2] See section II(B) below.

[3] See section II(C) below.

[4] See section II(A) below.

Defendants' experts have opined that OxyElite did not cause Ms. Van Houten's injuries.[5] As the deadline to identify experts has expired, these opinions are undisputed.

In sum, Ms. Van Houten's claims fail as a matter of fact and law because:

(1) She has not adduced expert testimony establishing general causation,

(2) Expert medical opinion confirms that OxyElite does not cause liver injury,

(3) She has not adduced expert testimony establishing specific causation, and

(4) Expert medical opinion confirms that Ms. Van Houten's alleged injuries were attributable to gallstone disease, not OxyElite.

II. UNDISPUTED FACTS [6]

A. The Bael tree, Aegeline, and OxyElite

The Bael tree is native to India and bears citrus-type fruit. The fruit, leaves, and bark of the Bael tree have been consumed as food throughout Southeast Asia since as early as

bael fruit

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[5] See section II(C) below.

[6] Where a particular statement of fact is not immediately followed by a citation, its citation is the first citation subsequent to that fact.

1500 BC.[7] The fruit is consumed in a variety of ways, is nutritious, and commonly used to treat upset stomachs.[8] A casual internet search reveals an abundance of products made from the Bael tree and its constituent ingredients. Aegeline has been isolated from the fruit, leaves, and bark of the Bael tree since 1952.[9]

Aegeline and seven other naturally occurring compounds are ingredients of OxyElite. Aegeline has undergone several pre-clinical studies, each indicating no adverse effects and no liver toxicity. These studies involved administering Aegeline to rats and rabbits at dosages which far exceed the proportionate human dosage of Aegeline contained in OxyElite. The animals sustained no injury. Similarly, a limited human pilot study was conducted where volunteers were treated with between 200mg to 800mg of Aegeline. The liver tests of participants remained normal throughout the course of consumption and no adverse effects

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[7] Roy, S.K., Bael, in, Fruits of India, Tropical and Subtropical 498 (Bose, T.K., ed., 1985); V. Singanan et al., The Hepatoprotective Effect of Bael Leaves (Aegle marmelos) in Alcohol Induced Liver Injury in Albino Rats, 2 Int'l J. Sci. Tech., No. 2, at 83 (2007), both attached as **Exhibit 1**.

[8] P.C. Sharma et al., A Review on Bael Tree 6 Nat. Prod. Radiance, No. 2, at 171-174 (2007), attached as **Exhibit 2**.

[9] A. Chatterjee & S. Bose, Studies on the Active Principles Isolated from the Leaves of Aezie Marmelos, Correa, 29 J. Indian Chem. Soc. 425 (1952), attached as **Exhibit 3**.

were reported.[10] Additionally, Ms. Van Houten conceded that as of October 2014, she was not aware of "any scientific studies, medical or laboratory tests, or chemical analysis" establishing Aegeline or OxyElite causes liver damage or injury.[11] To date, she has identified none. The undisputed evidence thus shows Aegeline and OxyElite do not generally cause liver injury.

B. Ms. Van Houten's Medical History

Ms. Van Houten's medical history is consistent with the foregoing conclusion as it shows a lack of specific causation. Ms. Van Houten identified **February 5th, 2013 through July 2013** as the period she used OxyElite. Her relevant medical history, however, begins in **March 2011**.

On March 21st, 2011, Ms. Van Houten was admitted to the Hilo Medical Center Emergency Department (**HMC**) with complaints of abdominal pain. She was diagnosed with cholelithiasis (gallstones), prescribed medication for pain and nausea, and was discharged. Her liver tests were within normal range.[12] Approximately one week later, Ms. Van Houten presented to HMC with sharp

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10 See section II(C) below.

11 See Plaintiff Everine Van Houten's Answers to Defendant USPlabs, LLC Request for Answers to Interrogatories, Nos. 12 & 13, attached as **Exhibit 4**.

12 See HMC 2011 Medical Records, Bates Stamp (**BS**) Nos. 634 - 644 (the lab results relevant to liver function include **bilirubin**, **AST**, and **ALT**, which are known as liver enzymes), attached as **Exhibit 5**.

abdominal pain and an ultrasound revealed gallstones. At this time, Ms. Van Houten elected surgery to address her gallstones, and on April 14th, 2011, her gallbladder was removed.[13]

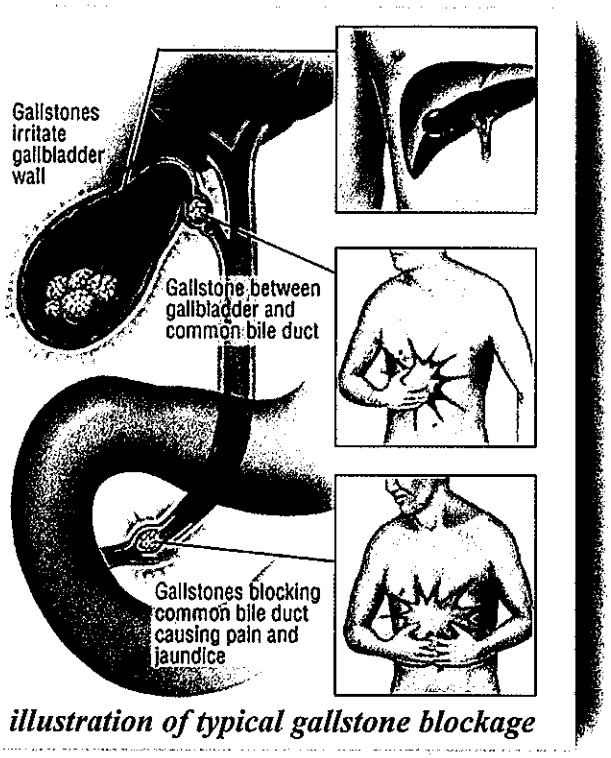

illustration of typical gallstone blockage

But, complications persisted. Ms. Van Houten returned to HMC twenty-four hours later with urinary retention, requiring the placement of a catheter.[14] Ms. Van Houten again returned to HMC a week after her surgery with complaints of abdominal pain reminiscent of her prior gallbladder pain. Liver tests revealed high enzyme levels.[15] An ERCP was performed and identified a possible stone retained in her bile dict.[16] She returned again to HMC on April 28th, 2011, with similar complaints of back and abdominal

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13 See id. at BS Nos. 186-191, attached as **Exhibit 5**.

14 See id. at BS No. 137, attached as **Exhibit 5**.

15 See id. at BS Nos. 49-50, attached as **Exhibit 5**.

16 See id. at BS No. 62, attached as **Exhibit 5**. Endoscopic Retrograde Cholangiopancreatography (ERCP) is a technique that combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems of the biliary or pancreatic ductal systems.

pain, as well as nausea, which were noted as complications from a retained stone. Tests again revealed high liver enzyme levels.[17]

On November 7th, 2012, Ms. Van Houten presented to HMC with complaints of pain during urination. Ms. Van Houten was diagnosed with a probable urinary tract infection.[18] Four months later, on March 18, 2013 she returned to HMC with complaints of abdominal pain, nausea, vomiting, and diarrhea. Three "non-obstructing left renal [kidney] stones" were detected and liver tests revealed high enzyme levels.[19] Liver tests on March 20th indicated her enzyme levels remained high.[20]

By April 4th, Ms. Van Houten's liver enzyme levels returned to within normal range.[21] However, she was back at HMC on April 5th, 2013 reporting moderate, constant abdominal pain, as well as nausea. Ms. Van Houten stated that since her gallbladder surgery, "the pain has been moderate and constant." She also reported "nausea associated with the pain," and dyspareunia (pain during

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17 See id. at BS Nos. 602-606 attached as **Exhibit 5**.

18 See HMC 2012-2013 Medical Records, BS Nos. 575-580, attached as **Exhibit 6**.

19 See id. at BS Nos. 525-0533, attached as **Exhibit 6**.

20 See id. at BS Nos. 502-510, attached as **Exhibit 6**.

21 See id. at BS Nos. 479-480, attached as **Exhibit 6**.

intercourse).[22] Her liver enzyme levels remained within normal range.[23]

On April 29th, 2013, Ms. Van Houten presented to HMC again with abdominal pain, nausea, and vomiting, noting that "her current pain feels very similar to her past gall stone [sic] pain."[24] Ms. Van Houten next presented to HMC on July 5th, 2013 with complaints of abdominal pain and three weeks of coughing. The medical provider noted that Ms. Van Houten "had some non-obstructing kidney stones on her last abdominal ultrasound a few weeks ago." Her liver enzyme levels tested high and a urinary tract infection was detected. Ultra sound images revealed a likely kidney stone.

Ms. Van Houten returned to HMC on July 9th and 16th, reporting abdominal pain. On July 9th, her liver enzyme levels were elevated, but by the 16th they returned to near normal ranges.[25] Ms. Van Houten again returned to HMC with abdominal pain at the end of the month and her liver enzyme levels were just above normal.[26]

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22 See id. at BS Nos. 465-466, attached as **Exhibit 6**. There appears to be a typo in the medical provider's note, which provides that Ms. Van Houten's gallbladder was removed two weeks prior. Ms. Van Houten's gallbladder surgery, however, occurred in 2011.

23 See id. at BS Nos. 468-469, attached as **Exhibit 6**.

24 See id. at BS Nos. 428-434, attached as **Exhibit 6**.

25 See id. at BS Nos. 351-356, 306-313, attached as **Exhibit 6**.

26 See id. at BS Nos. 269-0274, attached as **Exhibit 6**.

On August 2nd, 2013, Ms. Van Houten was examined by gastroenterologist William Hartman, M.D.. Regarding Ms. Van Houten's abdominal pain, Dr. Hartman noted, "[h]er symptoms have a clinical course of recurrent episodes of choledocholithiasis, ***symptoms she's had since April of 2011***." Dr. Hartman recommended another ERCP, which Ms. Van Houten elected to undergo.[27] The purpose of the ERCP was "to investigate possible retained common bile duct stone." The procedure instead identified a different abnormality, but was unable to correct it:

> Reintroduction of the guidewire into the biliary tree, it was clear that there was diversion along what appeared to be a cystic duct remnant that attached near the distal common bile duct. An attempt was then made to place a small stent into the biliary tree; however, for technical reasons, this could not be deployed and the process was abandoned.[28]

Hours after the ERCP, Ms. Van Houten experienced nausea and vomiting and returned to HMC. An examination on August 8th, 2013 provided Ms. Van Houten had a small gas bubble in the liver "consistent with recent ERCP and sphincterotomy" that was "suspicious for a very focal cholangitis [common bile duct infection]."[29]

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27 See Gastroenterology Records at BS Nos. 60-61 (emphasis added), attached as **Exhibit 7.**

28 See id. at BS Nos. 75-76, attached as **Exhibit 7.**

29 HMC 2012-2013 Medical Records BS Nos. 220 - 225 attached as **Exhibit 6.**

Months later, on April 4th, 2014, Ms. Van Houten reported to HMC again with right flank and abdominal pain beginning two days prior, as well as nausea and vomiting. She also reported a recent urinary tract infection and noted the presence of blood in her urine. A liver test revealed elevated enzymes levels. Ms. Van Houten was diagnosed at this time with "Renal colic on left side, Nephrolithiasis [kidney stones], and Abdominal pain."[30] She returned to HCC on April 11th, reporting the presence of blood in her urine. Her medical provider attributed this to a ureter stone, based on CT scans. Also identified was a "vague wedge shaped area of relatively decreased density," representing an "area of fatty liver infiltration." A follow-up liver ultrasound was recommended in six to twelve months' time.[31]

Just over a week later, Ms. Van Houten presented to HMC again with complaints of abdominal pain and nausea. The exact etiology of her pain was noted as unknown, but she was diagnosed again with kidney stones.[32] In early May of 2014 she returned to HMC on three occasions. On May 5th Ms. Van Houten reported blood in her urine. She appears to have undergone surgery on May 8th, implanting a stent to address her kidney stones. She presented to HMC

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30 See HMC 2014 Medical Records BS Nos. 177-183, attached as **Exhibit 8.**

31 See id. at BS Nos. 169-170, 174-175, attached as **Exhibit 8.**

32 See id. at BS Nos. 134-140, attached as **Exhibit 8.**

the two following days with complaints of left flank pain.[33]

C. Expert Opinions

The Scheduling Order filed May 21st, 2014 provided mandatory deadlines for expert evidence disclosure:

> 11. Pursuant to Fed. R. Civ. P. 26(a)(2), each party shall disclose to each other party the identity and written report of any person who may be used at trial to present expert evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence. The disclosures pursuant to this paragraph shall be according to the following schedule:
>
> **a.** All plaintiffs shall comply by March 23, 2015.
>
> **b.** All defendants shall comply by April 22, 2015.
>
> Disclosure of the identity and written report of any person who may be called solely to contradict or rebut the evidence of a witness identified by another party pursuant to subparagraphs a and b hereinabove shall occur within thirty (30) days after the disclosure by the other party.

(ECF No. 37). Ms. Van Houten failed to identify any expert or expert evidence by the court-established deadline of March 23, 2015.[34] See Declaration of Kevin W. Herring ¶ 4. Consequently, Plaintiff is precluded from introducing expert evidence at trial. See Fed. R. Civ. P 26(a)(2).

Nevertheless, Defendants obtained and timely identified three experts.

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[33] See id. at BS Nos. 129-131, 82-88, 54-56 (citations in chronological order), attached as **Exhibit 8.**

[34] Plaintiff has not filed a motion or otherwise requested an extension of the now–expired deadline.

Robert G. Gish, M.D. is a Clinical Professor of Medicine at the University of Nevada, Las Vegas, Senior Medical Director of St. Joseph's Hospital and Medical Center in Phoenix, Arizona, and a Clinical Professor of Medicine (Consultant), at Stanford Hospital and Medical Center. **Hartmut Jaeschke, Ph.D. ATS** is the Chairman of the Department of Pharmacology, Toxicology & Therapeutics in the College of Medicine at the University of Kansas Medical Center. **Noel S. Weiss M.D., Dr.PH**, is a Professor at the Department of Epidemiology, School of Public Health, University of Washington.

1. Dr. Gish Opinion: OxyElite did not cause Ms. Van Houten's injuries

Dr. Gish opines that Ms. Van Houten's injuries were not caused by OxyElite, and are instead the result of her pre-existing gallstone disease. Ms. Van Houten's gallstone disease led to the surgical removal of her gallbladder in 2011. Even after gallbladder removal, however, patients like Ms. Van Houten remain prone to bile duct stones.

Bile duct stones can block the common bile duct, causing abdominal pain and liver test abnormalities. Imaging such as CT or MR can "miss" bile duct stones if they have already passed or are below the detection limits of the machine. Additionally, none of OxyElite's components are known liver toxins. Therefore, to a very high degree of medical certainty, the abdominal pain and rapid spikes in

liver enzyme levels experienced by Ms. Van Houten during 2013 are consistent with recurrent symptoms of her preexisting gallstone disease.[35]

2. Dr. Jaeschke Opinion: The Product is not toxic

Dr. Jaeschke opines that none of OxyElite's components are known liver toxins. OxyElite's ingredients are Caffeine, Aegeline, Bauhinia Extract, Higenamine HCI, Hemerocallis Fulva extract, Yohimbe extract, Maltodextrin, and Silicon Dioxide. Aegeline is a component of the Bael tree's leaves and fruit. Bael extracts have demonstrated health benefits.

Aegeline has undergone several preclinical toxicity experiments. The preclinical studies indicated no adverse effects or liver toxicity. These studies showed that Aegeline is safe even when exposure is 10-30 times greater than the dosage contained in OxyElite. A limited human pilot study was conducted where volunteers were treated with 200mg and up to 800mg of Aegeline; no adverse effect or liver toxicity was observed.

Considering the long-standing use of Bael tree leaves and fruit, and the preclinical studies, to a reasonable degree of medical certainty, Aegeline and OxyElite are not liver toxic.[36]

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[35] See Gish Opinion, attached as **Exhibit 9**.

[36] See Jaeschke Opinion, attached as **Exhibit 10**.

3. Dr. Weiss Opinion: There is no epidemiological evidence to support general causation

In her Complaint, Ms. Van Houten alleges that an epidemiological investigation showed that the Product has been associated with liver damage.[37] However, Dr. Weiss opines that the Centers for Disease Control's report, "Acute hepatitis and liver failure of unknown etiology in Hawaii – 2013: Report of a Cluster Investigation," regarding the possible role of consumption of OxyElite in the etiology of liver failure in a number of Hawaii residents (**CDC Report**), is based on a flawed and unscientific "investigation."

Epidemiologic studies are an important source of information regarding the causes of illness in human beings. If these studies are large enough, and are designed and conducted in such a way as to minimize measurement error and other types of distortion, they can provide highly relevant information regarding the hazards resulting from a particular exposure in humans.

However, the investigation upon which the CDC Report is based was not designed or conducted in a way such that measurement errors or other distortions were minimized. Cases were defined as not only having sustained acute hepatitis and liver failure, but as having previously consumed a weight loss or muscle building dietary supplement. In other words, the investigation suffered from

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37 See First Amended Complaint, ¶ 1.2 (ECF # 48)

selection bias, distorting the conclusion such that it could ***only*** confirm the hypothesis. The investigation presented in the CDC Report did not have the potential to identify any cause of the purported liver failure outbreak in Hawaii.[38] Ultimately, even the CDC Report concluded that the etiology, or cause, was "unknown."

III. ARGUMENT

A. Defendants are entitled to summary judgment because Ms. Van Houten cannot establish causation, an essential element of her claim.

Summary judgment is appropriate because Ms. Van Houten cannot establish an essential element of her claims.

> [T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.

Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 2552, 91 L. Ed. 2d 265 (1986).

Causation is an essential element of Ms. Van Houten's claims. See e.g., In re Hawaii Fed. Asbestos Cases, 699 F. Supp. 233, 236 (D. Haw. 1988) aff'd, 960

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38 See Weiss Opinion, attached as **Exhibit 11.**

F.2d 806 (9th Cir. 1992) ("The rule in Hawaii is that the plaintiff need only show that a product is dangerously defective and that it was the proximate cause of the injury."); Akee v. Dow Chem. Co., No. CIV.00-00382 BMK, 2003 WL 21738603, at *8 (D. Haw. July 21, 2003) ("Under Hawaii law, to impose strict liability because of a design defect, a plaintiff must prove that the product was used in an intended or reasonably foreseeable manner, that the manufacturer breached its duty by producing a dangerously defective product, and that the defect was the proximate cause of plaintiff's injuries.").

Ms. Van Houten, as plaintiff, has the burden of proving causation. See Miyamoto v. Lum, 104 Haw. 1, 15, 84 P.3d 509, 523 (2004). The burden of production also rests on the plaintiff:

> Because plaintiffs bear the ultimate burden of proof on causation, [the defendant] had only to point to the absence of a genuine issue of material fact; it wasn't required to produce any evidence at all. Thus, the admissibility of [the defendant's] expert's affidavit is beside the point; the question is whether plaintiffs adduced enough admissible evidence to create a genuine issue of material fact as to whether [defendant's product] caused their injuries.

Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1315 (9th Cir. 1995) (citations omitted). However, Ms. Van Houten cannot establish medical causation absent expert evidence.

Causation "must be shown through expert testimony when causation is linked to a medical conclusion." Bynum v. Magno, 125 F. Supp. 2d 1249, 1261

(D. Haw. 2000); see also Domingo ex rel. Domingo v. T.K., 289 F.3d 600, 607-08 (9th Cir. 2002); Devine v. Queen's Med. Ctr., 59 Haw. 50, 51-52 574 P.2d 1352, 1353 (1978) ("Even when viewed in the light most favorable to the plaintiff, the record fails to reveal that the post-operative care and conduct of the defendants towards the plaintiff's decedent was a proximate or contributory cause of his death from pulmonary embolism.").

This court applies the requirement broadly, to any claim that requires the trier-of-fact to form a medical conclusion:

> Dr. Callan's contention that causation must be established through expert testimony (which he claims is lacking here) is only partly correct. **Causation must be shown through expert testimony when causation is linked to a medical conclusion.** For example, in *Devine v. Queen's Medical Center,* cited by Dr. Callan, the plaintiff was required to show by expert testimony that the negligent post-operative care of her husband resulted in his death. 59 Haw. 50, 574 P.2d 1352, 1353 (1978). **A jury could not be expected to independently come to the medical conclusion that a certain kind of post-operative care would result in death.**

Bynum, 125 F. Supp. 2d at 1261 (emphasis added); see also Allen v. Rivera, No. 1:05-CV-00146-SAB PC, 2014 WL 295173, at *6 (E.D. Cal. Jan. 27, 2014) (Interpreting Domingo, a Ninth Circuit medical malpractice case applying Hawaii law, as holding that competent expert testimony is required to establish ***medical causation*** between a particular event and ***any injury***).

The purpose of such a requirement is to avoid charging laymen, who by definition lack certain experience and education, with the burden of drawing conclusions which require the very thing that they lack. See Mamea v. United States, 781 F. Supp. 2d 1025, 1040 (D. Haw. 2011) ("lay jurors are ill prepared to evaluate complicated technical data for the purpose of determining whether professional conduct conformed to a reasonable standard of care and whether there is a causal relationship between the violation of a duty and an injury to the patient.") (internal quotations and citations omitted). The flip side of this requirement is its "common knowledge exception," which provides that expert evidence is not required where the trier-of-fact can arrive at a causal conclusion without any medical expertise. This exception applies in situations of doctors leaving sponges in surgery patients or mistakenly removing perfectly healthy limbs, and is rare in application. Craft v. Peebles, 78 Haw. 287, 298, 893 P.2d 138, 149 (1995). Unlike the situations of an obviously harmful action, the causation Ms. Van Houten alleges involves complex biological functions.

Surely, there are cases where proof of a "defect and causation may be provided by expert testimony or by circumstantial evidence." Acoba v. Gen. Tire, Inc., 92 Haw. 1, 17, 986 P.2d 288, 304 (1999). But, the instant matter is not such a case. Consider the situation where a defect is alleged to have caused an incident, like a car accident or mortar explosion, which then causes the medical injury:

DEFECT → INCIDENT → INJURY

In these cases, experts may be involved in determining whether a defect caused the incident. See Stewart v. Budget Rent-A-Car Corp., 52 Haw. 71, 76, 470 P.2d 240, 243 (1970) ("The most convincing evidence is an expert's pinpointing the defect and giving his opinion on the precise cause of the accident after a thorough inspection."). Cases involving ingested products, however, are distinguishable because the expert testimony on the alleged defect and medical causation are one in the same:

DEFECT → INJURY

In these cases, much like medical negligence, there is no crash or explosion, and expert testimony regarding medical causation is necessary for lay persons to render an informed causal conclusion.

Grant v. Pharmative, LLC, 452 F. Supp. 2d 903 (D. Neb. 2006) is factually similar to the case at bar and illustrates the need for expert evidence when a plaintiff brings claims of supplement-induced liver damage. The Grant plaintiff raised product liability claims against the maker of an herbal supplement, Black Kohosh, alleging the supplement caused autoimmune hepatitis that resulted in the need for a liver transplant. Grant, 452 F. Supp. 2d at 906. Since such claims involved "complex issues of toxicology and pharmacology that a lay person could not be expected to understand," the plaintiff was required to "prove [causation]

through expert testimony." Id. The Grant plaintiff, however, failed to provide ***admissible*** expert evidence regarding causation and the court granted summary judgment for the defendant:

> Without evidence to establish both general and specific causation, plaintiffs cannot survive defendants' motions for summary judgment. Plaintiffs' counsel acknowledged at oral argument that the case fails without expert testimony as to causation. Having excluded the testimony of Dr. Corbett and the testimony of Dr. Sorrell as to causation, plaintiffs have no evidence to establish either general or specific causation.

Grant, 452 F. Supp. 2d at 910. Ms. Van Houten has failed to produce ***any*** expert evidence and she is now precluded from doing so at trial. Consequently, her claims fail as a matter of law.

B. In the alternative, Ms. Van Houten cannot establish causation because her evidence is legally insufficient.

It is anticipated that Ms. Van Houten may contend she has already set forth specific facts that place causation in genuine dispute. However, such a contention fails to acknowledge the requirements of demonstrating medical causation. Superficially appealing hypotheses are not enough. The law demands more.

1. Ms. Van Houten's evidence is legally insufficient because it does not show general and specific causation.

In the Ninth Circuit, plaintiffs must "establish that the substance at issue was capable of causing the injury alleged (general causation), and that the substance caused, or was a substantial factor in causing, the specific plaintiff's injury

(specific causation)." See Avila v. Willits Envtl. Remediation Trust, 633 F.3d 828, 836 (9th Cir. 2011). The purpose of this two-part assessment is to decipher whether an association is actually causal rather than spurious: "an agent cannot be considered to cause the illness of a specific person unless it is recognized as a cause of that disease in general." Reference Guide on Epidemiology, Michael J. Saks, David L. Faigman, David H. Kaye, Joseph Sanders, Annotated Reference Manual on Scientific Evidence, 2004 WL 48155, 50).

Two Hawaii cases, Forsyth v. Eli Lilly & Co., No. CIV. 95-00185 ACK, 1998 WL 35152135 [39] and Larsen v. Pacesetter Sys., Inc., 74 Haw. 1, 25-29, 837 P.2d 1273, 1286-87, amended (Oct. 22, 1992), amended on reh'g in part, 74 Haw. 650, 843 P.2d 144 (1992), illustrate the general and specific causation analysis.

Forsyth involved an antidepressant drug that purportedly caused a man to kill his wife and himself. Forsyth, CIV. 95-00185 ACK, 1998 WL 35152135 at *1. The plaintiff offered an expert toxicologist's opinion to show the antidepressant ***specifically*** caused the man to kill himself. Id. at *11. The court found that the plaintiff's toxicologist opinion could only show ***general*** causation since the toxicologist did not conduct a direct psychological examination of the

[39] Not reported in the Federal Supplement.

man in question. Id. The court then concluded the toxicologist's opinion was unreliable under Daubert:

> Dr. Bost has published a few articles on this topic which have been published in peer-reviewed journals. Although subjected to peer review, there is no indication that Dr. Bost's theories have been accepted by other scientists. There is also no indication of the error rate of Dr. Bost's studies. In fact, Plaintiffs admit that Dr. Bost's methodology "consisted of counting the number of people who died with a particular drug or substance in their body, and then analyzing the data as a possible relation between drug and death." Opposition, at 49. This hardly seems to conform to scientific standards and would confuse the jury under F.R.E. 702. *Daubert,* 43 F.3d at 1320–1321.

Forsyth, at *11-12.

Similarly, in Larsen, the court provided that the policies underlying products liability could not be furthered by imposing liability in cases where general causation, but not specific causation, was shown:

> **In this case, as in *Khan* and *O'Brien*, plaintiff's injury was allegedly caused by the propensity of a product which was designed to be implanted in the body, to malfunction**. However, when the causal nexus between defect and injury is examined, both *Khan* and *O'Brien* are distinguishable from this case. In *Khan,* plaintiff had suffered no physical injury from surgery or product malfunction and complained solely of emotional distress caused by the knowledge that her heart valve might potentially malfunction. Allowing plaintiff to recover for emotional distress on the specific record before the court would allow *any* recipient of the same model heart valve to recover from the manufacturer.[ ] In *O'Brien,* plaintiff was not pacemaker dependent, his physician advised against replacement, and plaintiff's surgical injuries could be viewed as, in large part, self-inflicted. Thus, both *Khan* and *O'Brien* raised the issue of the fairness of imposing liability upon the manufacturer far in excess of the degree to which its product was actually defective.

> Accordingly, in both cases it was not clear whether imposing liability on the defendant would be consistent with and further the policy considerations supporting products liability.
>
> **In this case, unlike *O'Brien* and *Khan*, there is clear legal causation between plaintiff's injury and the alleged product defect.** Unlike the plaintiff in *O'Brien,* plaintiff's decision in this case to replace the device was forced upon him. Plaintiff was advised that he was in fact pacemaker dependent, Pacesetter expressly recalled its admittedly failure-prone product and recommended pacemaker replacement in such patients, and, in reliance on Pacesetter's advisory, plaintiff's physicians recommended that the Programalith III be replaced. Unlike the plaintiff in *Khan,* there are few problems of proof or unlimited liability. Plaintiff in this case suffered actual physical injuries as a result of his replacement surgeries, distinguishing him from the general class of persons with similar implants.
>
> Thus, the balance in this case is tipped toward imposing liability on Pacesetter. Plaintiff was in the limited class of pacemaker recipients who would almost certainly be injured by the pacemaker's potential to malfunction, and whose severe injuries were foreseeable, indisputable, and plainly caused by the pacemaker's condition. Imposition of liability in this case will therefore advance the policy goals of products liability by compensating consumers of defective products for personal injuries caused by the frustration of their reasonable expectations, and will do so fairly, on behalf of a limited and foreseeable group of product consumers.

Larsen, 74 Haw. at 27-28, 837 P.2d at 1287. Here, without any expert evidence, Ms. Van Houten can establish neither general nor specific medical causation. Consequently, summary judgment in favor of Defendants is appropriate and furthers the policy goals of products liability.

2. Ms. Van Houten's evidence is legally insufficient because it fails to show a causal relationship is more likely than not.

In Hawaii, expert evidence on medical causation must establish the causal nexus with "reasonable medical probability." Durham, No. CIV. 08-00342 JMS, 2011 WL 2532423, at *9. This is because "possibilities are endless in the field of medicine." Castro v. Melchor, 760 F. Supp. 2d 970, 993 (D. Haw. 2010). Thus, evidence must show the event or action is more likely to be a cause than not:

> Even when viewed in the light most favorable to [the Plaintiff], none of the testimony establishes that [the alleged medical injury] is more likely to follow from [the alleged medical cause] than from a more rapid process [(an alternative to the alleged medical cause)]. . . . [A]ll of the experts stated that they could not say with reasonable scientific probability that [the alleged cause] increased the likelihood of [the alleged injury].
>
> In light of Hawaii's requirement of medical testimony to establish causation, there was insufficient testimony to create a genuine issue of material fact regarding causation. Summary judgment in favor of the defendants was appropriate.

Domingo, 289 F.3d at 607-08.

Here, if the opinion of Ms. Van Houten's treating physician is to be considered, it is insufficient to show causation. As Ms. Van Houten conceded: "My doctor didn't give me an exact diagnosis, but said my illness **could** be caused by [OxyElite.]"[40] At best, this indicates a possibility, which is insufficient as a

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[40] Plaintiff Everine Van Houten's Answers to Defendant USPlabs, LLC Request for Answers to Interrogatories, No. 11 (emphasis added).

matter of law.

Additionally, the "greater than 50 percent" admissibility threshold applies equally to epidemiological evidence:

> The Court notes at the outset that the Ninth Circuit in *Daubert* has set forth guidelines regarding the reliability of epidemiological studies: this circuit requires more than a 50% probability of causation, which means that epidemiological evidence must show that the risk of an injury or condition in the exposed population was more than double the risk in the unexposed or control population.

Forsyth, No. CIV. 95-00185 ACK, 1998 WL 35152135, at *9 (citing Daubert, 43 F.3d at 1320–1321.

In Forsythe and Daubert, the plaintiffs' causal theories relied heavily on epidemiological evidence to establish that a drug caused depression and birth defects, respectively. See id. Epidemiological evidence uses statistics to show that an event or action somehow caused damage when the specific explanation is scientifically unknown. See Daubert, 43 F.3d at 1314. However, the statistics must be sufficiently compelling. Id. ("Causation can be proved even when we don't know precisely *how* the damage occurred, if there is **sufficiently compelling proof** that the agent must have caused the damage *somehow*." (some emphasis added)). Epidemiological evidence is sufficiently compelling if it shows the population exposed to the event or action is twice as likely to sustain injury as the non-exposed population:

> None of plaintiffs' epidemiological experts claims that ingestion of Bendectin during pregnancy more than doubles the risk of birth defects. To evaluate the relationship between Bendectin and limb reduction defects, an epidemiologist would take a sample of the population and compare the frequency of birth defects in children whose mothers took Bendectin with the frequency of defects in children whose mothers did not. The ratio derived from this comparison would be an estimate of the "relative risk" associated with Bendectin. For an epidemiological study to show causation under a preponderance standard, "the relative risk of limb reduction defects arising from the epidemiological data ... will, at a minimum, have to exceed '2'." That is, the study must show that children whose mothers took Bendectin are more than twice as likely to develop limb reduction birth defects as children whose mothers did not. **While plaintiffs' epidemiologists make vague assertions that there is a statistically significant relationship between Bendectin and birth defects, none states that the relative risk is greater than two. These studies thus would not be helpful, and indeed would only serve to confuse the jury, if offered to prove rather than refute causation.**

Daubert, 43 F.3d at 1320-21 (citations and footnotes omitted) (emphasis added).

Ms. Van Houten has not provided sufficiently compelling epidemiological evidence, because, simply, she has provided no baseline against which her causal claims can be measured. Additionally, the CDC Report Ms. Van Houten alleges shows an association between OxyElite and liver injury concludes the cause of the purported cluster of liver damage is unknown.[41] This is far from sufficiently compelling.

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41 See section II(c) above.

3. Ms. Van Houten's evidence is legally insufficient because it is unreliable.

"The court has the responsibility of acting as a gatekeeper to prevent unreliable expert testimony from reaching the jury." Durham v. County of Maui, 742 F. Supp. 2d 1121, 1127 (D. Haw. 2010). Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) established a flexible two-pronged test for determining whether expert testimony is relevant, reliable, and helpful to the trier of fact. See id.

First, "the expert's methods must be adequately explained." Durham, 742 F. Supp. 2d at 1128. Factors the court may consider are methodology, testing, peer review and publication, error rates, and 'acceptability' in the relevant scientific community. Id. There must be sufficiently compelling proof that the product caused the medical injury:

> It is true, as [the plaintiff] contends, that *Daubert* does not require that every aspect of a theory of medical causation be supported by research on the identical point, and that it is not necessary to show how a particular act or event caused an injury. There must, however, be "sufficiently compelling proof that the [event] must have caused the damage somehow." The reasoning between steps in a theory must be based on objective, verifiable evidence and scientific methodology of the kind traditionally used by experts in the field.

Domingo, 289 F.3d at 607 (emphasis and citations omitted).

Second, the court must assess whether the expert evidence proffered is relevant and helpful to the trier-of-fact. "This inquiry is not merely a reiteration of

the relevancy inquiry—[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses." Durham, 742 F. Supp. 2d at 1128 (internal quotation and citation omitted).

Ms. Van Houten has provided no expert evidence. As a result, there are no methods, principles, or practices for the court to assess. See Durham, 742 F. Supp. 2d at 1128 (expert's methods must be adequately explained and reflect reliable scientific practices). In Domingo, the court held expert evidence unreliable and therefore inadmissible where, as here, there was no means for the court to objectively analyze a causal theory:

> As the district court noted, there was no evidence of widespread acceptance of Dr. Harrington's theory linking extended malleting to FES; indeed, no theory linking extensive malleting to FES had ever been published. The court also noted the lack of any objective source, peer review, clinical tests, establishment of an error rate or other evidence to show that Dr. Harrington followed a valid, scientific method in developing his theory.

Domingo, 289 F.3d 600, 606 (9th Cir. 2002).

Additionally, Ms. Van Houten's evidence is unreliable because it does not address alternate causes. For specific causation evidence to be admissible, it must address alternate causes. In Lopez v. Wyeth–Ayerst Labs., the court excluded testimony of a medical expert under Rule 702 because his testimony was not based

on reliable epidemiological evidence and failed to "eliminate all other potential causes" of the plaintiff's condition. Lopez v. Wyeth–Ayerst Labs., No. C 94-4054 CW, 1996 WL 784566, at *3 (N.D. Cal. Dec. 13, 1996) aff'd sub nom. Lopez v. Wyeth-Ayerst Labs., Inc., 139 F.3d 905 (9th Cir. 1998). Since the plaintiff's expert stated that 30-40% of the medical injury had idiopathic or unknown causes, and the defense expert provided uncontroverted evidence that there were no epidemiological studies showing the link between the product at issue and medical injury as alleged by the plaintiffs, the plaintiff's expert's failure to rule out alternate causes was "particularly troubling." Id. Considering Ms. Van Houten's pre-existing gallbladder disease, the failure to produce any expert evidence on medical causation is more than particularly troubling; it counsels nothing short of summary judgment in Defendants' favor.

IV. CONCLUSION

For the reasons discussed above, this claim is legally insufficient to proceed to trial. Therefore, Defendants request that summary judgment be entered in their favor on all claims.

DATED: Honolulu, Hawaii; April 22, 2015.

/s/ Kevin W. Herring
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